UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL No. 2804
THIS DOCUMENT RELATES TO:	Case No. 1:17-md-2804
Track Three Cases	Judge Dan Aaron Polster

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF CRAIG MCCANN

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It is undisputed that McCann has neither opinions nor expertise when it comes to the validity of any of the "red flags" Plaintiffs' counsel instructed him to use. It is also undisputed that no expert has ever disclosed the 27 "red flags" Plaintiffs relied on to come up with their June 2020 disclosure of flagged prescriptions—and continue to rely on to identify the 884,166 prescriptions at issue at trial. In fact, Plaintiffs now concede they have ***no*** expert testimony to support ***any*** of those so-called "red flags." Nor do Plaintiffs point to a single document containing the actual parameters they told McCann to use.

Instead, Plaintiffs argue that they ***do not need*** expert testimony to support their contention that the 27 "red flags" McCann relies on are, in fact, red flags that a pharmacist should have investigated. But any testimony purporting to identify "red flags" applicable to all opioid prescriptions filled by each Defendant can only be the subject of expert testimony, requiring specialized knowledge and experience in pharmacy practice and pharmacists' professional judgment. FED. R. EVID. 701 (c) & 702(a); *United States v. White*, 492 F.3d 380, 403-04 (6th Cir. 2007) (expert qualification under Rule 702 is required whenever an opinion "call[s] for specialized skill or expertise" or requires the witness to "apply knowledge and familiarity . . . well beyond that of an average lay person"). McCann has no such expertise, and Plaintiffs now admit that no expert has applied any such expertise to the 27 "red flags."

The Court should exclude McCann's dispensing analyses in their entirety as arbitrary, unreliable, and unsupported by expert testimony. At a bare minimum, the Court should bar McCann and Plaintiffs from referring to any unvalidated algorithm—or to the results of applying any unvalidated algorithms to Defendants' dispensing data—as a "red flag."

I. McCann's Analyses Based on the 27 Unvalidated "Red Flags" Are Necessarily Unreliable, Irrelevant, and Not Helpful to the Factfinder

Plaintiffs take the remarkable position that—separate and apart from the opinions of purported subject-matter experts like Carmen Catizone—McCann's math is sufficient to identify how many prescriptions Defendants' pharmacists should have flagged, thus demonstrating the magnitude of each Defendant's misconduct, including each Defendant's pharmacists' violation of their "corresponding responsibility" under DEA regulations. Opp. Br. at 5-6.[1] Plaintiffs are, of course, correct that those issues go to the "pertinent inquiry" at trial, which is the "precondition to admissibility" for an expert's testimony. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 (1993). The problem for Plaintiffs is that McCann's narrow expertise in data analysis is entirely disconnected from any of those issues.

In fact, Plaintiffs' elaborate characterizations of McCann's opinions and the import of his numbers would surely be a surprise to McCann himself, who not only has said nothing of the sort, but who has also repeatedly disavowed any such opinions:

> Q. You don't have any opinion that any of those prescriptions should not have been filled, correct?
>
> A. Correct.
>
> Q. No opinion that any of them are illegitimate?
>
> A. Correct.
>
> Q. No opinion that any of them were diverted?
>
> A. Correct.
>
> ***Q. You have no opinion that there was anything at all wrong with those prescriptions?***
>
> ***A. Correct.***

[1] In their opposition brief, Plaintiffs describe McCann's analyses as illuminating "prescriptions that Defendants should have identified and investigated," Opp. Br. at 1, "the magnitude of Defendants' wrongful conduct," *id.* at 5, "the magnitude of Defendants' breach of their corresponding responsibility," *id.* at 6, "the scope and breadth of the Defendants' due diligence failures and excessive dispensing," *id.*, "potentially suspicious prescriptions," *id.*, and "prescriptions that should have been red-flagged by Defendants," *id.* at 10. The Court should ignore Plaintiffs' characterizations and focus on McCann's own testimony, set forth in the above text.

Dkt. 3866-4, McCann Tr. at 138:3-14 (emphasis added). The reality is that McCann's math is only as reliable, relevant, and helpful as the methodologies Plaintiffs' counsel gave him, because McCann has no independent expertise or opinions about what his numbers signify.

A. The 27 "red flags" are deficient because no expert has validated them.

Any testimony suggesting that the 27 algorithms reflect "red flags" that a pharmacist should have investigated was required to be supported by an expert disclosure grounded in pharmacy expertise. But Plaintiffs concede that no expert has ever disclosed, much less validated, any of those 27 algorithms. That should be the end of the inquiry. At a bare minimum, the Court should not allow Plaintiffs to refer to these 27 algorithms—or to McCann's results based on those algorithms—as "red flags" when no expert in pharmacy practice has ever identified or validated them.

Plaintiffs say not to worry, because these 27 "red flags" are "based upon" or "supported by" various industry and government documents, including Defendants' own systems and policies. Opp. Br. at 3. Defendants disagree, but this is beside the point. The fact remains that Plaintiffs do not (and cannot) argue that ***McCann*** has any expertise with which to evaluate any Defendant's systems or industry documents to formulate an opinion about appropriate "red flag" algorithms for pharmacy practice. If he purported to offer any such opinions, the Court would have to exclude them as beyond his training or experience. And once again, Plaintiffs misleadingly attribute knowledge and opinions to McCann that he has explicitly disavowed. *See* Ex. 1, McCann Tr. at 106:21-107:4 (testifying that he "didn't put together the flagging criteria reflected in [his] report based on [his] own review or [his] staff's review of documents and other sources," that he "received these flagging methods from counsel," and that he "do[es]n't know how they assembled them"); Dkt. 3866-4, McCann Tr. at 88:9-89:5 (testifying that he doesn't

know "who put those [27] red flag criteria together," that "they were provided . . . to my office by counsel," and that "how they assembled those 27 from different sources, I don't know").

In the end, all Plaintiffs can muster to defend McCann's analyses based on the 27 "red flags" is ***counsel's opinion*** that those algorithms are appropriate "red flags" because they fall into "broad categories" of red flags Defendants or their trade organization have acknowledged, Opp. Br. at 1-2, or because a handful of them "relate to" red flags discussed in the documents of some (not all) Defendants, *id.* at 2-5.[2] Of course, counsel's opinions are wholly irrelevant. In any event, superficial correspondence with "broad categories" is beside the point: ***Categories of red flags***—such as "Doctor Shopping, Pharmacy Shopping, Pattern Prescribing, Excessive Dispensing, Suspicious Combinations, and Cash Payments," *id.* at 2—are not at all the same as ***the specific mathematical algorithms*** counsel instructed McCann to use. Of course, counsel's instructions are not a valid methodology under Rule 702. *See supra* Section I.D.

Tellingly, Plaintiffs do not point to a single document containing the actual parameters found in McCann's report. In fact, many of the examples they cite illustrate the varying approaches Defendants took with respect to any given "category." For instance, in the "Pattern Prescribing" category, Plaintiffs rely on a Walgreens document referring to an "[i]ncreased frequency of prescriptions for the same controlled drug by one prescriber," a Walmart document discussing "the same medication, dosage, and directions for a large number of individuals," and a Rite Aid document talking about "writ[ing] for the same or similar medications in the same dosage quantities to most or all of his/her patients." Opp. Br. at 4-5. Plaintiffs identify no allegedly supporting documents from either CVS or Giant Eagle. *See id.* None of these

[2] Plaintiffs' opposition lumps together the 27 original "red flags" in their June 2020 disclosure with the 16 new "red flags" from Catizone's expert report. They discuss only 5 of the 27 unvalidated "red flags" (4, 5, 6, 12, 13) but 8 of the 16 "red flags" from Catizone (22, 23, 24, 25, 26, 27, 28, 39). *See* Opp. Br. at 3-5.

documents come anywhere close to describing the parameters McCann actually applied (with no attempt to validate them):

> 12) An opioid was dispensed to ***at least 4 different patients on the same day*** and the opioid prescriptions were for the same base drug, strength and dosage form and were written by the same prescriber."
>
> 13) An opioid was dispensed to ***at least 3 different patients within an hour*** and the opioid prescriptions were for the same base drug, strength and dosage form and were written by the same prescriber."

Dkt. 3866-9, McCann Report at 152 (emphasis added).

If it can be done at all, distilling "broad categories" or synthesizing divergent approaches within the industry into actionable, across-the-board "red flag" algorithms requires expert testimony. *White*, 492 F.3d at 400-04. That is precisely what Catizone attempted to do for the 16 "red flags" described in his expert report, purporting to use his specialized knowledge and experience in pharmacy practice to review Defendants' documents and formulate specific algorithms for application to Defendants' dispensing data. *See* Dkt. 3866-11, Supplemental Report of Carmen Catizone at 31-51.[3] It is what Plaintiffs needed to do for ***any*** red flag algorithm they hoped to rely on at trial. If the 27 "red flags" Plaintiffs' counsel gave to McCann were really as "widely recognized" as Plaintiffs assert, Opp. Br. at 2, presumably Catizone would have validated and incorporated them into his expert report. He did not.

B. These flaws necessarily infect Plaintiffs' chosen "compilation" approach.

The lack of any expert validation for the initial 27 "red flags" infects the universe of "compilation" prescriptions on which McCann and Plaintiffs will rely at trial—because the entire aggregate is defined by "red flags" that no expert has validated. There is no basis in pharmacy

[3] Plaintiffs appear to suggest a previously undisclosed distinction in McCann and Catizone's opinions: that the initial 27 "red flags" show what Defendants "could have" flagged based on their own documents or policies while the 16 "red flags" from Catizone show what Defendants "should have" flagged. *See* Opp. Br. at 5-6. Apart from the obvious disconnect between Defendants' documents and the specific algorithms used by McCann, this distinction shows up nowhere in McCann or Catizone's reports or testimony and thus should be stricken in its entirety.

practice—and certainly no valid connection to the pertinent inquiry in the case—to arbitrarily manipulate the universe of allegedly improper prescriptions in the way McCann has done.

Plaintiffs try to get around this fact by calling the "compilation" prescriptions a "Test Group." *Id.* But the 884,166 "compilation" prescriptions in McCann's final report are not merely a sample or subset of the allegedly improper prescriptions at issue at trial; they are the *only* prescriptions at issue at trial. Any suggestion to the contrary is not only in direct violation of this Court's orders on Defendants' motions to strike, but also contrary to Plaintiffs' own election and representations to the Court and Defendants. *See* Dkt. 3726; Dkt. 3743 at 1.

Plaintiffs argue that McCann's artificial limitation of the universe of prescriptions is not a flaw because each of the 884,166 "compilation" prescriptions still "triggered one of the 16 flags discussed in the April Catizone Report." Opp. Br. at 7. But this argument ignores the purported relevance of McCann's analysis, which is to "help the jury understand the scope and breadth of the Defendants' due diligence failures and excessive dispensing." *Id.* at 6. By Plaintiffs' own admission, McCann's final analysis—for no reason even arguably connected to the disputed issues in this case—does not identify the actual "scope and breadth" of prescriptions Catizone believes were improper or should have been flagged. *Id.* at 7. That result is ***not*** the product of reliable principles or methods under *Daubert* or Rule 702. It is completely arbitrary.

C. These flaws are entirely of Plaintiffs' own making.

Plaintiffs try to blame Defendants—and even the Court—for McCann's flawed "compilation" methodology. *See id.* at 8 (arguing that Defendants' objection is "to the summary compilation the Court ordered and permitted the Plaintiffs to use"); *id.* at 8 (complaining that the "compilation" approach "was proposed by the very Defendants that now object to its use").

Plaintiffs' blame is both wrongly placed and immaterial. It is wrong because the flaws in McCann's methodology are entirely the result of Plaintiffs' own untimely disclosures and choice

of remedy. As Plaintiffs acknowledge, the Court provided Plaintiffs three separate options in response to Defendants' meritorious motion to strike. Opp. Br. at 8. No one forced Plaintiffs to select the option they did. *Id.* at 8 n.18 (admitting that they "chose option 2," the "overlapping prescriptions" option). If they could not support that option with timely disclosed expert testimony, they should have chosen one of the other avenues provided by the Court.[4]

Plaintiffs' blame game is also immaterial. The Court's proper decision to cure the prejudice of an untimely disclosure by imposing limits on the scope of trial evidence is entirely separate from the question of whether an expert opinion is reliable under *Daubert* and Rule 702. Unsurprisingly, Plaintiffs cite no authority for the proposition that Defendants' suggestion of a discovery sanction for Plaintiffs' untimely disclosure forecloses an argument that the resulting analysis based on an arbitrary manipulation of data is unreliable and inadmissible.

D. The flaws in McCann's methodology go squarely to admissibility.

Plaintiffs' final argument is that, even accepting that McCann's methodology is flawed, those flaws go only to the weight of his opinions and not their admissibility. In Plaintiffs' view, all that matters is if McCann did his math right and correctly followed instructions, because disputes over "data selection" are not grounds for exclusion. Opp. Br. at 9-10.

But Plaintiffs' argument assumes that this is a dispute over the interpretation or quality of the underlying data. It is not. The problem is not what data McCann started with but what he *did* with the data and what Plaintiffs intend to present to the jury: a heavily manipulated output that limits the actual universe of allegedly improper prescriptions to those triggering so-called

[4] Plaintiffs do not even try to dispute the procedural history laid out in Defendants' opening brief. Br. at 2-4. That history makes clear that none of this would have happened if Plaintiffs had timely disclosed the "red flags" on which they wished to rely, or if they had disclosed an expert willing to validate the 27 "red flags" they did timely disclose.

"red flags" that have never been validated for reasons and that have no connection whatsoever to the facts at issue in the case.

Nor are Defendants confusing the "*credibility and accuracy*" of McCann's methods with their "*reliability*," as Plaintiffs charge. Opp. Br. at 9 (quoting *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008)) (emphasis in original). To the contrary, Defendants' concerns go *directly* to reliability: whether McCann's opinions are the "product of reliable principles and methods" that were "applied . . . reliably to the facts of the case." FED. R. EVID. 702 (b), (c). As explained in the notes to Rule 702, "*any* step that renders the analysis unreliable . . . renders the expert's testimony inadmissible." FED. R. EVID. 702 advisory committee's note, 2000 amend.

By analogy, say the "pertinent inquiry" in a case was the number of traffic accidents involving red cars. Now suppose that an expert witness—for reasons unconnected from her expertise or the facts of the case—limited her purported estimate of "red car accidents" to those that involved *both* a red car *and* a yellow car. Such an "estimate" would not be the product of reliable methods reliably applied to the facts, nor would it be helpful to the jury in determining the number of "red car" accidents. But that is exactly what McCann has done.

The arbitrary limitation Plaintiffs' counsel directed McCann to apply does not reflect the reliable application of expertise to the facts in this case. It is not based on reliable principles or methods, and Plaintiffs have not identified any. Consequently, it does not illuminate the pertinent inquiry for the jury. Each of these failings goes squarely to admissibility.

II. McCann's Analyses Based on Catizone's 16 "Red Flags" Are Flawed Too

Plaintiffs rightly do not dispute that the Court should exclude an expert opinion to the extent it relies on the inadmissible opinions of another expert witness. *See Sims v. Kia Motors of America, Inc.*, 839 F.3d 393, 405 (5th Cir. 2016) ("[T]he district court properly excluded [the expert's] theory . . . because it relied on [another expert's] inadmissible . . . theory."); *Rink v.*

Cheminova, 400 F.3d 1286, 1294 (11th Cir. 2005) (experts were "properly excluded" when the relevance of their opinions relied on the opinions of an excluded expert).

For all the reasons stated in Defendants' separate motion and reply brief, Catizone's opinions should be excluded in their entirety. Without Catizone to connect McCann's analyses of the 16 "red flags" to the "pertinent inquiry" in the case—whether Defendants improperly filled opioid prescriptions that were subsequently diverted—McCann's opinions are entirely unreliable, disconnected from the facts at issue, and should be excluded.

CONCLUSION

For these reasons, the Court should exclude McCann's opinions and proposed testimony. In the alternative, and at a bare minimum, the Court should preclude Plaintiffs, McCann, or any other expert from referring to an unvalidated algorithm—or to the results of applying an unvalidated algorithm to Defendants' dispensing data— as a "red flag" at trial.

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Respectfully submitted,

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